AMENDMENTS

IN THE CLAIMS

1. (previously presented) A process for making torsemide modification II comprising torsemide modification I at less than about 0.5 weight%,

comprising the steps of:

(a) adding a crude torsemide modification II to a solvent mixture comprising acetonitrile and water;

(b) isolating torsemide modification I;

(c) suspending the torsemide modification I of step (b) in water to form a solution;

(d) adjusting the solution of step (c) to a pH of about 10±0.2;

(e) filtering the solution of step (d);

(f) adjusting the solution of step (e) to a pH of 6.25±0.2; and

(g) isolating torsemide modification II comprising torsemide modification I at less than about 0.5 weight%.

2. (previously presented) A stable pharmaceutical formulation comprising an effective amount of torsemide modification II and a pharmaceutically acceptable excipient wherein the excipient has a low moisture content.

3. (previously presented) The stable pharmaceutical formulation of claim 2, wherein the excipient having a low moisture content is selected from the group consisting of lactose anhydrous, crospovidone, povidone, microcrystalline cellulose, and magnesium stearate.

4. (original) The stable pharmaceutical formulation of claim 2 comprising torsemide modification II in an amount of about 2.5 mg to about 200 mg per tablet.

5. (original) The stable pharmaceutical formulation of claim 4 comprises torsemide modification II in an amount of about 2.5 mg, about 5 mg, about 10 mg, about 20 mg or about 100 mg per tablet.

6. (previously presented) A stable pharmaceutical formulation comprising an effective amount of torsemide modification II wherein no more than 15% of the torsemide modification II rearrange into another form of torsemide during storage under stress conditions for at least 3 months, wherein the stress conditions are about 40°C and about 75% relative humidity.

7-8. (canceled)

9. (currently amended) ~~The~~ A stable pharmaceutical formulation ~~of claim 6~~ comprising an effective amount of torsemide modification II wherein no more than 15% of the torsemide modification II rearrange into torsemide modification I upon storage under stress conditions for at least 3 months, wherein the stress conditions are about 40°C and about 75% relative humidity.

10. (original) The stable pharmaceutical formulation of claim 9 wherein not more than 5% of the torsemide modification II rearranges into torsemide modification I.

11. (previously presented) The stable pharmaceutical formulation of claim 6 wherein the torsemide modification II is selected from the group consisting of high purity torsemide modification II and torsemide modification II containing torsemide modification I at trace amounts, wherein the high purity torsemide modification II contains less than about 0.5 weight% torsemide modification I, and wherein the trace amounts of torsemide modification I is about 0.5 weight% to about 2 weight%.

12. (currently amended) The stable pharmaceutical formulation of claim 11 wherein the torsemide modification II is torsemide modification II containing ~~comprises about 0.5 to about 2% (w/w) of~~ torsemide modification I at trace amounts.

13. (original) The stable pharmaceutical formulation of claim 6 wherein the torsemide modification II has a particle size distribution such that 100 % is below 200μ.

14. (original) The stable pharmaceutical formulation of claim 13 wherein the particle size distribution is such that 100% is below 100μ.

15. (original) The stable pharmaceutical formulation of claim 14 wherein the particle size distribution is such that 100% is below 50μ.

16. (previously presented) Torsemide modification II comprising torsemide modification I at less than about 0.5 weight%.

17. (previously presented) The torsemide modification II of claim 16 which is a stable polymorphic form of torsemide.

18. (previously presented) The torsemide modification II of claim 17, wherein no more than 15% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage under stress conditions for at least 3 months, wherein the stress conditions are about 40°C and about 75% relative humidity.

19. (canceled)

20. (previously presented) The torsemide modification II of claim 18 which is in the form of fine crystals.

21. (previously presented) The torsemide modification II of claim 18 wherein not more than 15% of the torsemide modification II rearranges into torsemide modification I during storage under stress conditions for at least 3 months.

22. (previously presented) The torsemide modification II of claim 21 wherein not more than 10% of the torsemide modification II rearranges into torsemide modification I during storage under stress conditions for at least 3 months.

23. (previously presented) The torsemide modification II of claim 17 which is further characterized by having a particle size distribution such that 100 % is below 200μ.

24. (previously presented) The torsemide modification II of claim 23 which is further characterized by having a particle size distribution such that 100% is below 100μ.

25. (previously presented) The torsemide modification II of claim 24 which is further characterized by having a particle size distribution such that 100% is below 50μ.

26. (previously presented) Torsemide modification II comprising torsemide modification I at less than about 0.5 weight% produced according to the process of claim 1.

27. (previously presented) The torsemide modification II of claim 26 which is a stable polymorphic form of torsemide.

28. (previously presented) The torsemide modification II of claim 27, wherein not more than 15% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage under stress conditions for at least 3 months, wherein the stress conditions are about 40°C and about 75% relative humidity.

29. (canceled)

30. (previously presented) The torsemide modification II of claim 28 which is in the form of fine crystals.

31. (canceled)

32. (currently amended) The torsemide modification II of claim 28 wherein not more than 10% of the ~~high purity~~ torsemide modification II rearranges into torsemide modification I during storage under stress conditions for at least 3 months.

33. (previously presented) The torsemide modification II of claim 32 which is further characterized by having a particle size distribution such that 100 % is below 200μ.

34. (previously presented) The torsemide modification II of claim 33 which is further characterized by having a particle size distribution such that 100% is below 100μ.

35. (previously presented) The torsemide modification II of claim 34 which is further characterized by having a particle size distribution such that 100% is below 50μ.

36-38. (canceled)

39. (previously presented) The torsemide modification II of claim 22, wherein not more than 5% of the torsemide modification rearranges into torsemide modification I during storage at 40°C and 75% relative humidity for at least 3 months.

40-42. (canceled)

43.(previously presented) The torsemide modification II of claim 32, wherein not more than 5% of the torsemide modification rearranges into torsemide modification I during storage at 40°C and 75% relative humidity for at least 3 months.

44.(previously presented) The torsemide modification II of claim 16, wherein not more than 15% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage at 40°C and 75% relative humidity for at least 3 months.

45.(previously presented) The torsemide modification II of claim 44, wherein not more than 10% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage at 40°C and 75% relative humidity for at least 3 months.

46.(previously presented) The torsemide modification II of claim 44, wherein not more than 5% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage at 40°C and 75% relative humidity for at least 3 months.

47.(previously presented) The torsemide modification II of claim 44, wherein not more than 2% of the torsemide modification II rearranges into any other polymorphic form of torsemide during storage at 40°C and 75% relative humidity for at least 3 months.

48.(previously presented) The torsemide modification II of claim 16, wherein not more than 15% of the torsemide modification II rearranges into torsemide form 1 during storage at 40°C and 75% relative humidity for at least 3 months.

49.(previously presented) The torsemide modification II of claim 48, wherein not more than 10% of the torsemide modification II rearranges into torsemide form 1 during storage at 40°C and 75% relative humidity for at least 3 months.

50. (currently amended) The stable pharmaceutical formulation of claim 11, the torsemide modification II containing torsemide modification I at trace amounts, wherein the trace amounts is about 0.5 weight% to about 2 weight%, and wherein the formulation further comprises a combination of excipients selected from lactose anhydrous NF, crospovidone NF, ~~providone NF,~~ povidone USP and microcrystalline cellulose NF.

51. (previously presented) The stable pharmaceutical formulation of claim 50, containing a moisture content of 0.5-1.5%.

52. (new) A stable pharmaceutical formulation comprising an effective amount of torsemide and a pharmaceutically acceptable carrier, wherein the torsemide is torsemide modification II that does not undergo any significant rearrangement into other polymorphic forms of torsemide upon storage for at least 3 months at 40° C and 75% relative humidity.

53. (new) The stable pharmaceutical formulation of claim 52 wherein the torsemide is greater than 98% torsemide modification II.

54. (new) The stable pharmaceutical formulation of claim 53 wherein the torsemide is greater than 99.5% torsemide modification II.

55. (new) The stable pharmaceutical formulation of claim 52, 53 or 54 wherein said pharmaceutically acceptable carrier has a low water content.

56. (new) The stable pharmaceutical formulation of claim 55 wherein said carrier having a low water content is selected from lactose anhydrous, crospovidone, povidone, cellulose, and magnesium stearate.

57. (new) The stable pharmaceutical formulation of claim 52, 53 or 54 wherein said formulation is a tablet.

58. (new) The stable pharmaceutical formulation of claim 57 wherein the torsemide modification II is present in an amount of 2.5 to 200 mg per tablet.

59. (new) The stable pharmaceutical formulation of claim 58 wherein the torsemide modification II is present in an amount of 100 mg per tablet.

60. (new) The stable pharmaceutical formulation of claim 58 wherein the torsemide modification II is present in an amount of 5 mg per tablet.

61. (new) The stable pharmaceutical formulation of claim 58 wherein the torsemide modification II is present in an amount of 2.5 mg per tablet.

62. (new) The stable pharmaceutical formulation of claim 52, 53 or 54 wherein the torsemide modification II does not substantially rearrange into torsemide modification I.

63. (new) The stable pharmaceutical formulation of claim 52, 53 or 54 wherein the torsemide modification II has a particle size distribution wherein 100% is below 200 μm.

64. (new) The stable pharmaceutical formulation of claim 63 wherein the torsemide modification II has a particle size distribution wherein 100% is below 100 μm.

65. (new) The stable pharmaceutical formulation of claim 64 wherein the torsemide modification II has a particle size distribution wherein 100% is below 50 μm.

66. (new) The stable pharmaceutical formulation of claim 52, 53 or 54 having an *in vitro* dissolution rate, when measured by the USP Paddle Method at 50-90 RPM in 900 mL water is not less than 80% (by weight) of the torsemide modification II released after 30 minutes.

67. (new) The stable pharmaceutical formulation of claim of claim 66 wherein the *in vitro* dissolution rate does not substantially change over time.

68. (new) The stable pharmaceutical formulation of claim 67 wherein the *in vitro* dissolution rate does not substantially change for at least 3 months.

69. (new) A method of treating edema in a patient comprising administering an effective amount of the stable pharmaceutical formulation of claim 52, 53 or 54 to the patient.

70. (new) The stable pharmaceutical formulation of claim 9 wherein the torsemide modification II is selected from the group consisting of high purity torsemide modification II and torsemide modification II containing torsemide modification I at trace amounts, wherein the high purity torsemide modification II contains less than about 0.5 weight% torsemide modification I, and wherein the trace amounts of torsemide modification I is about 0.5 weight% to about 2 weight%.

71. (new) The stable pharmaceutical formulation of claim 70 wherein the torsemide modification II is torsemide modification II containing torsemide modification I at trace amounts.

72. (new) The stable pharmaceutical formulation of claim 9 wherein the torsemide modification II has a particle size distribution such that 100 % is below 200μ.

73. (new) The stable pharmaceutical formulation of claim 72 wherein the particle size distribution is such that 100% is below 100μ.

74. (new) The stable pharmaceutical formulation of claim 73 wherein the particle size distribution is such that 100% is below 50μ.